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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,733	11/02/2001	Sunanda R. Kulkarni	MCP-291	3078

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,733	KULKARNI ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8,13,17,37-43,45 and 47-49* is/are pending in the application.

4a) Of the above claim(s) *37-43,45 and 47-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 8, 13 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 7/26/04 canceled claims 22, 23, 28 and 32. Claims 1-6, 9-12, 14-16, 18-21, 24-27, 29-31, 33-36, 44 and 46 have been previously canceled.

Claims in the application are 7, 8, 13, 17, 37-43, 45 and 47-49.

Claims 37-43, 45 and 47-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 6 of 3/4/03.

Claims examined on the merits are 7, 8, 13 and 17.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC . 103

Claims 7, 8, 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cayle (3,718,739) in view of Schwartz et al (4,034,035) and Bowman (3,954,979) for reasons in the previous office action of 4/27/04 and for reasons herein.

The claims are drawn to a tablet or composition containing about 3000 to 9000 FCC lactase units, about 25-70 weight percent microcrystalline cellulose, and a lubricant. Also present may be materials selected from a group of including fillers, lubricants and gums.

Cayle discloses making tablets containing lactase. A composition from which the tablet is made contains lactase mixed with conventional solid fillers or carriers such as cornstarch, talc, calcium phosphate

and calcium sulfate (paragraph bridging cols 3 and 4). In Example 6 (col 9, lines 10-20), tablets are disclosed containing lactase, cornstarch, magnesium stearate and gelatin.

Schwartz et al disclose preparing tablets (col 1, line 6 and col 2, line 17) containing a lubricant (col 2, line 41), a mixture of microcrystalline cellulose and modified cornstarch in a ratio of microcrystalline cellulose to cornstarch of about 1:3 to 3:1 (col 3, lines 5-10), and an enzyme (3, line 66).

Bowman discloses (col 3, lines 5-49) dehydrating an admixture of yeast and vitamins under conditions that do not inactivate enzymes in the yeast, grinding the dehydrated product to produce a granular product, admixing the dried granular product with a diluent, and forming the resultant dry blend into tablets. The diluent can be selected from corn or potato starch, microcrystalline cellulose and mixtures thereof, and is preferably a mixture of corn or potato starch and microcrystalline cellulose in a ratio of from 20:80 to 80:20 (col 4, lines 25-30).

It would been obvious to replace a portion of the cornstarch in the lactase-containing tablet of Cayle (Example 6) with microcrystalline cellulose as suggested by Schwartz et al and Bowman preferring a mixture of corn starch and microcrystalline cellulose when preparing tablets containing an enzyme or material containing an enzyme. Using ratios of microcrystalline cellulose to cornstarch in the ratio ranges of Schwartz et al and Bowman would have inherently resulted in an amount of microcrystalline cellulose within the range

of about 25 to 70% by weight as claimed. Cayle disclose that lactase LU/gram can be 50,000 or 500,000 to 600,000 (col 5, lines 40-45). It would have been obvious to provide a tablet having a preferred optimum amount of lactase units such as 3,000 to 9,000 FCC units since Cayle disclose that the unit dosage should be sufficient to hydrolyze the lactose present (col 4, lines 40-45). The magnesium stearate in Example 6 of Cayle is a lubricant, and the amount used is within the percent by weight range of claim 17. The members of the Markush group of claim 8 include cornstarch that would have been provided when using a mixture of cornstarch and microcrystalline cellulose as set forth above. Furthermore, Cayle discloses (paragraph bridging cols 3 and 4) other members in the group of the claims, and these are conventional solid fillers and carriers.

Response to Arguments

Applicants urge that in Example 6, Cayle obtains a tablet containing 500 LU/tablet. However, Cayle discloses that lactase activities of 500,000 to 600,000 LU/gram can also be obtained. It would have been obvious to use one gram of the 500,000 to 600,000 LU/gram lactase in Example 6 when a higher amount of lactase activity is desired, and this would have resulted in 5,000 to 6,000 LU/tablet. Cayle suggests that the unit oral dosage of lactase should be sufficient to hydrolyze lactose present in a subject. Selecting a preferred optimum lactase dosage per tablet would have required only limited routine experimentation and been within the ordinary skill of

the art. There is seen no unexpected result in the presently claimed 3000 to 9000 FCC lactase units per tablet.

Double Patenting

Claims 7, 8, 13 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,365,208 B1 or claims 1-8 of U.S. Patent No. 6,057,139 or claims 1-7 of U.S. Patent No. 6,660,313 B1 in view of Schwartz et al and Bowman, and if necessary in further view of Cayle.

The claims of the patents require formulations containing lactase and microcrystalline cellulose.

It would have been obvious to provide the claimed formulations of the patents in tablet form in view of Schwartz et al and Bowman producing enzyme-containing tablets containing microcrystalline cellulose, and if necessary in further view of Cayle producing a tablet contain lactase.

Response to Arguments

Applicants state that the option of filing a terminal disclaimer will be addressed when the claims are otherwise allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date

of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
10/8/04